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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/277,575 03/26/99 NEWELL

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EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/277,575

Applicant(s)
Newell

Examiner
Mary B. Tung

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 9, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 18, 29, 39, 44, 47, 49-53, 74, 140, and 143-148 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-14, 18, 29, 39, 44, 47, 49-53, 74, 140, and 143-148 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152).
- 20) ☐ Other: _____

DETAILED ACTION

Claims 1-142 were originally presented.

Claims 15-17, 19-28, 30-38, 40-43, 45, 46, 48, 51, 54-73, 75-78, 80-139, 141 and 142 were cancelled in the paper filed July 13, 1999, Paper No. 3.

Claims 1-14, 18, 29, 39, 44, 47, 49-53, 74, 79 and 140 are pending.

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's election of Group II, claims 12-18 in the paper filed May 18, 2001, Paper No. 7 is acknowledged. However, upon reconsideration, the following restriction is required under 35 U.S.C. § 121:

- I. Claims 1-3, 5, 8-13, 39 and 44, and new claims 143-148 are drawn to a method for decreasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DR molecule and an HLA-DR inducing agent, wherein said agent is adriamycin, classified in class 424, subclass 34 and 514, subclass 21.
- II. Claims 1-3, 6, 8-13, 39 and 44, and new claims 143-148 are drawn to a method for decreasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DR molecule and an HLA-DR inducing agent, wherein said agent is gamma interferon, classified in class 424, subclass 85.5 and class 514, subclass 21.
- III. Claims 1-4, 7-13, 39 and 44, and new claims 143-148 are drawn to a method for decreasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DR molecule and an HLA-DR inducing agent, wherein said agent is a UCP expression vector, classified in class 435, subclass 320.1 and class 514, subclass 21.
- IV. Claims 1-4, 7-13, 39 and 44, and new claims 143-148 are drawn to a method for decreasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DR molecule and an HLA-DR inducing agent,

- wherein said agent is a TCR $\alpha\beta$ engagement molecule, classified in class 424, subclass 144.1 and class 514, subclass 21.
- V. Claims 1-4, 7-13, 39 and 44, and new claims 143-148 are drawn to a method for decreasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DR molecule and an HLA-DR inducing agent, wherein said agent is a fatty acid, classified in class 514, subclass 21.
- VI. Claims 14, 47 and 49-52 are drawn to a drawn to a method for increasing mitochondrial potential by the administration of a major histocompatibility class II HLA-DP/DQ molecule, classified in class 514, subclass 21.
- VII. Claims 18 and 29, drawn to a method for lysis of a mammalian cell using a major histocompatibility class II HLA-DR ligand, classified in class 435, subclass 375.
- VIII. Claims 53 and 140, drawn to a drawn to a method for selectively killing a Fas-ligand bearing tumor cell using acetate, classified in class 435, subclass 375.
- IX. Claims 74 and 79, drawn to a composition comprising an HLA-DR inducing agent and an HLA-DR ligand, classified in class 530, subclass 350.
2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I-VIII are unique methods. They differ with respect to ingredients, process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.
4. Groups IX and I-VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the HLA-DR ligand can be used in a method of protein purification using affinity chromatography.
5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classifications, and because a non-patent literature and/or sequence search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.
6. Should Applicants traverse on the ground that the members of the groups are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art,

the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

NOTE: the common subject matter of Groups 1-VIII will be examined only to the extent of the elected invention.

Conclusion

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

August 1, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

Mary B. Tung
MARY BETH TUNG, PH.D.
PATENT EXAMINER